BIDIRECTIONAL STEERABLE CATHETER WITH SLIDABLE MATED PULLER WIRES

FIELD OF THE INVENTION

The present invention relates to catheters having a steerable tip section and, more particularly, to an improved bidirectional steerable catheter.

BACKGROUND OF THE INVENTION

Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

In use, the electrode catheter is inserted into a major vein or artery, e.g., the femoral artery, and then guided into the chamber of the heart which is of concern. Within the heart, the ability to control the exact position and orientation of the catheter tip is critical and largely determines how useful the catheter is.

Steerable catheters are generally well-known. For example, U.S. Patent No. RE 34,502 describes a catheter having a control handle comprising a housing having a piston chamber at its distal end. A piston is mounted in the piston chamber and is afforded lengthwise movement. The proximal end of the catheter body is attached to the piston. A puller wire is attached to the housing and extends through the piston and through the catheter body. The distal end of the puller wire is anchored in the tip section of the catheter to the side wall of the catheter shaft. In this arrangement, lengthwise movement of the piston relative to the housing results in deflection of the catheter tip section. The design described in RE 34,502 is generally limited to a catheter having a single puller wire.

Bidirectional steerable catheters are also generally well-known, as a variety of designs have been proposed. In many such designs, e.g., as described

in U.S. Patent Nos. 6,066,125, 6,123,699, 6,171,277, 6,183,463 and 6,198,974,all of which are incorporated herein by reference, a pair of puller wires extend through a lumen in the main portion of the catheter shaft and then into opposing off axis lumens in a deflectable tip section where the distal end of each puller wire is attached to the outer wall of the deflectable tip. Pulling one wire in a proximal direction causes the tip to deflect in the direction of the off axis lumen in which that wire is disposed.

In other designs, e.g., as described in U.S. Patent No. 5,531,686, the puller wires are attached to opposite sides of a rectangular plate that is fixedly mounted at its proximal end and extends distally within a lumen in the tip section. In this arrangement, pulling one of the wires proximally causes the rectangular plate to bend in the direction of the side to which the pulled puller wire is attached, thereby causing the entire tip section to deflect.

In all of the designs for a steerable catheter, the puller wire or wires are attached at their distal ends to some structure in the tip section of the catheter. Such designs require time, effort and expense to make such attachments. It would be useful to provide a steerable tip catheter that does not require that the puller wires be fixedly attached to the catheter tip section.

SUMMARY OF THE INVENTION

The invention is directed to an improved steerable catheter, particularly a bidirectional steerable catheter. The catheter comprises an elongated, tubular catheter body having at least one lumen extending therethrough and a flexible tubular tip section having at least one lumen extending therethrough. The catheter body and tip sections may be a single structure or separate structure wherein the tip section is fixedly attached to the distal end of the catheter body. Whether by the use of a more flexible material for the tip section or the inclusion of a stiffening structure in the catheter body, the tip section is more flexible than

the catheter body.

The catheter further comprises first and second puller wires having proximal and distal ends. Each puller wire extends from a control handle at the proximal end of the catheter body through a lumen in the catheter body and into a lumen in the tip section. Along the length of the portion of the puller wires that extend through the catheter body and tip section, the puller wires are slidably mated. As usual herein, "mated" means that the puller wires are maintained in a closely adjacent relationship. Such a relationship can be maintained by an arrangement wherein the puller wires have an interlocking relationship with each other. Alternatively, the puller wires may be disposed in a tubular sleeve dimensioned so as to maintain the puller wires in close adjacent relationship. The distal ends of the puller wires are fixedly attached to each other.

Proximal movement of the thumb control relative to the handle housing results in proximal movement of the first piston and first puller wire relative to the handle housing and catheter body, which results in deflection of the tip section in the direction of the lumen into which the first puller wire extends. Distal movement of the thumb control relative to the handle housing results in distal movement of the first piston, causing proximal movement of the second piston and puller wire relative to the handle housing and catheter body, which results in deflection of the tip section in the direction of the lumen into which the second puller wire extends.

The control handle comprises means for pulling at least one of the puller wires in a proximal direction and preferably, means for pulling one puller wire in a proximal direction while simultaneously pushing the other puller wire in a distal direction. A particularly preferred handle comprises one or more generally circular gears having teeth that engage teeth along a proximal portion of the puller wires or to engage teeth along a bar or rod to which each puller wire is

attached. The gear or gears are arranged so that by rotation of the one gear or one of a plurality of gears causes the first and second puller wires to move in opposite directions, one proximally and the other distally. As a result, the tip section deflects in the direction of the puller wire that moves proximally.

DESCRIPTION OF THE DRAWINGS

These and other features of the advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of the catheter of the invention;

FIG. 2 is a side cross-sectional view of the junction of the proximal section and tip section of an embodiment of a catheter according to the invention;

FIG. 3 is a transverse cross-sectional view of the proximal section shown in FIG. 2 taken along line 3-3;

FIG. 4 is a side cross-sectional view of the distal end of the tip section shown in FIG. 2;

FIG. 5 is a transverse cross-sectional view of the tip section shown in FIG. 4 taken along line 5-5;

FIG. 6 is a side cross-sectional view of one embodiment of an interlocking puller wire pair according to the invention;

FIG. 7 is a side cross-sectional view of another embodiment of a mated puller wire pair according to the invention;

FIG. 8 is a side cross-sectional view of another mated puller wire pair according to the invention;

FIG. 9 is a schematic depicting the deflection of the tip section according to an alternative embodiment of the invention;

FIG. 10 is a perspective view of a gear arrangement useful for manipulating the puller wires of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In a particularly preferred embodiment of the invention, there is provided a steerable bidirectional electrode catheter. As shown in **FIG. 1**, a preferred catheter comprises an elongated catheter body **10** having a proximal section **12**, a distal tip section **14**, and a control handle **16** at the proximal end of the proximal section **12**.

As shown in **FIGs. 2 and 3**, the proximal section **12** comprises an elongated tubular construction having a single axial or central lumen **18**. The proximal section **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The proximal section **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** preferably comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the proximal section **12** so that when the control handle **16** is rotated the tip section **14** will rotate in a corresponding manner.

The overall length and diameter of the catheter may vary according to the application. A presently preferred catheter has an overall length ranging from about 90 to about 120 cm, more preferably from about 100 to 110 cm. The outer diameter of the proximal section **12** is not critical, but is preferably no more than about 8 French. The inner surface of the outer wall **20** may optionally be lined with a stiffening tube **22** as described in more detail in U.S. Pat. No. 5,897,529, the disclosure of which is incorporated herein by reference. The stiffening tube **22** may be made of any suitable material, but preferably is made of polyimide or nylon. The stiffening tube **22**, along with the braided outer wall **20**, provides improved flexural and torsional stability while at the same time minimizing the wall thickness of the catheter body **12**, thus maximizing the diameter of the central lumen **18**. The outer diameter of the stiffening tube **22** is about the same as or slightly smaller than the inner diameter of the outer wall **20**. A

particularly preferred catheter **10** has an outer diameter of about 0.092 inch and a central lumen **18** diameter of about 0.052 inch. The stiffening tube **22** is optional and may be omitted.

As shown in **FIGs. 4 and 5**, the tip section **14** comprises a short section of flexible tubing **24** having a single lumen **26** extending therethrough, although additional lumens can be included if desired. The flexible tubing **24** is made of a suitable non-toxic material that is more flexible than the proximal section **12**. A presently preferred material for the tubing **24** is polyurethane. The outer diameter of the tip section **14**, like that of the proximal section **12**, is preferably no greater than about 8 French, more preferably about 6½ French or less.

In the embodiment shown, the tip section **14** and the proximal section **12** are separate structures that have been fixedly attached to each other. It is understood that the tip section **14** and proximal section **12** could be formed as a unitary structure as desired. To attach the tip section **14** to the proximal section **12**, the proximal end of the tip section **14** comprises an outer circumferential notch **28** that is received in a corresponding inner circumferential notch **29** at the distal end of the proximal section **12**. The tip section **14** and proximal section **12** may be attached by glue or the like.

As shown in **FIG. 4**, the tip section **14** carries a tip electrode **38** and a ring electrode **40**. The length of the tip electrode **38** is not critical and will depend on the desired application for which the catheter is to be used. Preferably the tip electrode **38** has an exposed length ranging from about 2 mm to about 6 mm. Mounted along the length of the tip section **14** is ring electrode **40**. The length of the ring electrode **40** similarly is not critical, but preferably ranges from about 0.5 mm to about 3 mm. Additional ring electrodes can be provided if desired. If multiple ring electrodes are used, they are spaced apart in any fashion as desired so long as their edges do not touch.

The tip electrode **38** and ring electrode **40** are each electrically connected

to a separate lead wire **30**. Each lead wire **30** extends through the lumen **26** in the tip section **14** and the central lumen **18** in the proximal section **12** and into the control handle **16**. The proximal end of each lead wire **30** is connected to an appropriate connector **(not shown)**, which can be plugged into or otherwise connected to a suitable monitor, source of energy, etc., within or outside the control handle **16**.

To deflect the tip section **14**, there is provided a pair of puller wires **34a** and **34b** that extend through the catheter body **12** and into the tip section **14**. The puller wires **34** are made of any suitable metal, such as stainless steel or Nitinol. Preferably each puller wire **34** has a lubricious coating of, e.g., Teflon® or the like. Each puller wire **34** extends from the control handle **16**, through the central lumen **18** in the proximal section **12** of the catheter body and into the lumen **26** of the tip section **14**. At least the portions of the puller wires that extend through the proximal section **12** and tip section **14** are slidably mated to each other. At their distal ends, the two puller wires **34a and 34b** are fixedly attached to each other at a joint **34c** by soldering, welding or the like. The puller wires **34** can have any desired cross-sectional shape, e.g., round, rectangular, etc. Further, the cross-sectional shape of the first puller wire **34a** need not be the same as that of the second puller wire **34b**.

There are several ways in which the puller wires can be mated along their length. For example, in one embodiment, as shown in **FIG. 6**, the puller wires **34a** and **34b** are interlocked. In this embodiment, puller wires **34a** and **34b** are both rectangular in cross-sectional shape. The first puller wire **34a** has a generally circular notch **35** along its length extending inwardly from the surface facing the second puller wire **34b**. The second puller wire **34b** comprises a rib **37** having a generally circular cross-section that extends outwardly from the surface facing the first puller wire **34a** and into notch **35**. Notch **35** and rib **37** are sized to allow the first and second puller wires to slide freely relative to each other, but

to prevent the puller wires from separating.

In another preferred embodiment, as shown in **FIG. 7**, rectangular puller wire **34a** has a pair of generally rectangular notches **38** that receive mating rectangular ribs **39** of puller wire **34b**. In this embodiment, because the puller wires are not interlocking, a tube or sleeve **40** is provided that surrounds the puller wires to keep them in a closely adjacent relationship. The sleeve **40** may be made of any suitable material, e.g., polyimide or polyurethane or may take the form of a compression coil. The sleeve **40** may be of any appropriate shape, e.g., rectangular, as shown. The sleeve **40** preferably extends the full length of the portion of the puller wires **34** within the catheter body and may extend into the handle. The composition of the sleeve **40** may be consistent throughout or may vary. For example, a stiff sleeve, e.g., made of polyimide, may surround the puller wires throughout the proximal section **12** of the catheter body and a more flexible sleeve, e.g., made of polyurethane, may surround the puller wires **34** in the tip section **14**. Rather than a sleeve, the puller wires **34** may extend through a lumen in the proximal section of the catheter body and/or the catheter tip section that has a size and shape that maintains the puller wires **34** in close adjacent relation. It is understood that the puller wires **34a** and **34b** could be disposed within a sleeve in the proximal section **12** of the catheter body **10** and then extend into a lumen in the tip section that is sized and shaped to maintain the close relationship of the puller wires.

With reference to **FIG. 8**, there is shown yet another exemplary embodiment of a mated puller wire pair. In this embodiment, the puller wires **34a** and **34b** are both semi-circular in cross-section and are maintained in close adjacent relation by a generally circular sleeve **40**.

As can be seen, the cross-sectional shape of the puller wires can vary as desired. Preferably, the shape of the puller wires is selected to promote deflection of the tip section in a single plane. In this regard, puller wires having

a generally rectangular cross-section or at least one flat longitudinal surface are preferred. Alternatively or additionally, the cross-section of configuration of the sleeve can be chosen to promote deflection in a single plane. By using a sleeve having a rectangular or oval cross-sectional configuration, puller wires having a circular cross-sectional shape (or other shape that does not promote deflection of the tip section in a single plane) can be used and still result in a deflection generally within a single plane.

The puller wires of the present invention need not have a constant cross-sectional shape or size throughout their length. For example, in one exemplary embodiment, the puller wires are generally circular in cross-section over the length that extends through the proximal section **12** of the catheter body **10**, and then flatten out (generally like a boat oar) into a generally rectangular cross-sectional configuration in the tip section **14**.

The distal ends of the puller wires are fixedly secured to each other at joint **34c** by soldering, welding or any other suitable means. The distal end of the mated puller wire pair need not be anchored in the tip section of the catheter, but may be if desired. If anchored, any conventional technique for anchoring a puller wire in a tip section of a catheter may be used.

In another alternative embodiment, as depicted in **FIG. 9**, two mated pairs of puller wires **34** are provided. The first pair of mated puller wires are secured together at their distal ends, as discussed above, and extend to a first location **44** generally at the distal end of the tip section **14**. The second pair of mated puller wires are secured together at their distal ends, as discussed above, and extend to a second position **42** generally at about the midpoint of the tip section **14**. The first puller wire pair can be used to deflect the distal end of the tip section **14** in one of two possible opposing directions. The second puller wire pair can be used to deflect the proximal end of the tip section **14** in one of two possible opposing directions. This arrangement allows the tip section to be

deflected or bent at two locations. The bends may be in the same direction or in opposite directions as shown in **FIG. 9.** It is understood that the locations of the distal ends of the puller wire pairs can vary as desired.

The puller wires extend proximally from the catheter body into a suitable control handle where the puller wires may remain adjacent to each other or may be separated, depending on the design of the control handle. Typically, the proximal ends of the puller wires will be connected to structures that can be moved to apply a proximally directed force on one of the puller wires. Longitudinal movement of a puller wire **34** in a proximal direction relative to the catheter body section **12** results in deflection of the tip section **14.**

Examples of other suitable control handles that can be used with the present invention are described in U.S. Patent Nos. 6,123,699, 6,171,277, 6,183,463, and 6,198,974, the disclosures of which are incorporated herein by reference.

It is presently preferred to utilize a control handle that simultaneously applies a force to one puller wire of a puller wire pair in a proximal direction while applying a force to the second puller wire of the puller wire pair, i.e., a handle that pulls one wire and pushes the other wire at the same time. An example of such a handle utilizing a single gear arrangement is described in U.S. Patent No. 6,468,260 and U.S. Patent Application Serial No. 60/133,182, the disclosures of which are incorporated herein by reference.

With respect to **FIG. 10,** there is shown a gear arrangement useful for simultaneous pulling of one puller wire and pushing of the other. In this embodiment, the proximal end portions of each puller wire **34a** and **34b** comprise a plurality of gear teeth. The puller wire pair extends between first and second gears **50** and **51**, each having teeth that engage the teeth of puller wires **34a** and **34b** respectively. A third gear **52** simultaneously engages the teeth of the first gear **50** and second gear **51** such that rotation of the third gear in one direction,

e.g., clockwise, results in rotation of both the first and second gears in the opposite direction, e.g., counter-clockwise. This, in turn, results in longitudinal movement of one puller wire in a proximal direction and the other in a distal direction. Rotation of the third gear can be accomplished by means of a know or handle that is fixally attached to the third gear and extends to the outside of the handle housing where it can be manipulated by an operator.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fairest scope.